BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO
Division of Implant Manufacturing & Testing, Inc.

17 Seventeenth St.
Port Huron, MI 48060 (810) 982-7777 Fax (810) 982-7794

SEP - 8 2004

K041936
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510K Summary of Safety and Effectiveness

Date Prepared: Friday, November 21, 2003

Company name and contact:

Biopro, Inc.
17 17th Street
Port Huron, MI 48060
(P)810-982-7777
(F)810-982-7794

Contact Person : David Mrak, Director of Product Development

Proprietary Name: Biopro Sub-talar Implant

Common Name: Flatfoot Implant

Classification name: Screw, Fixation, Bone (per CFR section 888.3040)

Predicate Device:

The Biopro Sub-talar Implant is substantially equivalent in design, composition and function to other orthopedice screws manufactured and approved for maket such as: KMI Subtalar MBA System™ K960692 and the Kalix® implant K001231

Device Description:

The Biopro Sub-talar Implant is a combination of three components. Two components made of titanium allow and one component made of UHMW Polyethylene.
It will be provided in a range of diameters, including 8mm-12mm in diameter. The device will be cannulated for precise implantation. The device is implanted using a standard 0.125" square driver which is cannulated.

Intended use:

The Biopro Subtalar Implant will be used on indications that are common with presently marketed devices. The primary indications for use of the Biopro Subtalar Implant is as a spacer for stabilixation of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Possible Adverse Effects

The following are specific adverse effects which should be understood by the surgeon and explained to the patient. These do not include all adverse effects which can occur with surgery in general, but are important considerations particular to metallic internal stabilization devices. General surgical risks should be explained to the patient prior to surgery.

1. Infection
2. Pain discomfort or abnormal sensations due to presence of the implant
3. Metal sensitivity or allergic reaction to a foreign body
4. Migration of the implant loosening of the implant
5. Delayed correction in alignment
6. Decrease in bone density due to stress shielding
7. Bursitis

Packaging:
Each of the BioPro Subtalar Implants should be received in an intact package: Damaged packages or products should not be used and should be returned to Biopro.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Mr. David Mrak
Director of Product Development
Biopro, Inc.
17 Seventeenth Street
Port Huron, Michigan 48060

Re: K041936
Trade Name: Biopro Subtalar Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: July 12, 2004
Received: July 28, 2004

Dear Mr. Mrak :

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

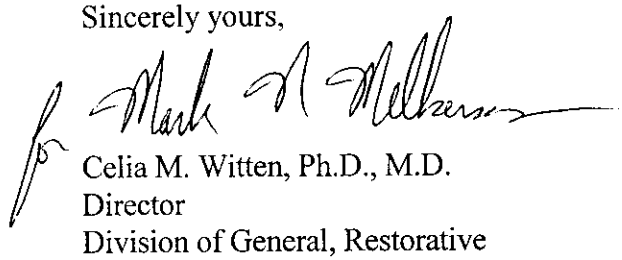
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041936

Indications For Use

The Biopro subtalar implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. Conditions include:

Flat foot treatment in children and adolescents
Congenital flat foot
Unsuccessful long term orthopedic treatment (orthodics)
Tarsal coalitions
Painfully flat foot
Supple deformity in posterior tibial tendon dysfunction
Paralytic flat foot
Subtalar instability

(Division Sign-Off)
Division of General, Restorative
And Neurological Devices

510K Number K041936

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K041936

Prescription Use X (Per 21 CFR 801.109) Or Over-the-Counter__